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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,968	05/14/2001	Jan Raa	CU-2535 WDD	9869

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/854,968	Applicant(s) RAA ET AL	
	Examiner Abdel A. Mohamed	Art Unit 1653	

-- The MAILING DATE of this c mmunication appears n the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 17-32* is/are pending in the application.

4a) Of the above claim(s) *9 and 22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT, RESTRICTION REQUIREMENT, STATUS OF THE APPLICATION AND CLAIMS

1. This is a divisional application of U.S. Serial No. 09/061,575, filed 4/16/98, now U.S. Patent No. 6,376,650. The preliminary amendment filed 5/14/01 and the response to the restriction requirement, filed 4/15/02, respectively are acknowledged, entered and considered. In view of Applicant's request claims 1-8 and 10-16 have been canceled. Thus, claims 9 and 17-32 are now pending in the application.

CLAIMS STAND WITHDRAWN WITHOUT TRAVERSE

2. Claims 9 and 22-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 4, filed 4/15/02. Thus, the Office action is directed to the merits of claims 17-21 (Group II) as per elected invention and Applicant is requested to cancel non-elected claims 9 and 22-32 in the next communication.

CLAIM REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 appears to be a product-by-process claim, but there is no active method step(s) recited in the claim, except for the recitation "produced by enzymatic hydrolysis.....".

Claims 17 and 21 recite the limitation " the hydrolytic enzyme" in lines 5-6 of claim 17 and "said hydrolytic enzyme" in lines 1-2 of claim 21, respectively. There are insufficient antecedent basis for these limitations in claim 17 or claim 21. Further, claims 17 and 21 recite the term "derived". Amendment of the claims to recite "obtained" is suggested.

Claim 18 is indefinite in the recitation "wherein said peptide consists of less that about 100 amino acid units..." because it is not clear if it refers to a mixture of peptides" or to "a bioactive peptide"? Appropriate clarification is required. Further, the phrase is indefinite and grammatically incorrect in the recitation "consists of less that about 100 amino acid units". Amendment of the claim to recite "consists of less than 100 amino acid units" or "consists about 100 amino acid units" is suggested.

Claim 18 s also indefinite in the recitation "a molecular weight below 10,000" because it is not clear if the claim is referring to Dalton or Kilodalton. Further, the method used to determine the molecular weight should be identified because the molecular weight observed may vary slightly depending on the techniques used in performing the analysis.

Claim 19 is indefinite in the recitation "wherein said aromatic amino acids is at least one acid selected from the groups consisting of tyrosine, phenylalanine and arginine." because the claim as drafted uses improper Markush format. Further, the term "at least one acid" appears to be typographical error because there is no proper antecedent basis for "one acid" in claim 19 or claim 17. Thus, amendment of the claim to recite "wherein said aromatic amino acids is selected from the group consisting of tyrosine, phenylalanine and arginine" is suggested.

CLAIMS REJECTION-35 U.S.C. § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimaki et al. (U.S. Patent No. 4,016,147).

The instantly claimed invention is directed to a bioactive peptide composition consisting essentially of a mixture of peptides having an aromatic amino acid in the N-terminal position, produced by enzymatic hydrolysis of a protein source at pH in the range of 1-6 with less than 100 amino acid units and has a molecular weight below 10,000 (claim 18), wherein the aromatic amino acid is selected from the group consisting of tyrosine, phenylanaline and arginine (claim 19), wherein the protein source is fish (claim 20).

Similarly, the reference of Fujimaki et al. discloses a bioactive composition produced by hydrolysis of a protein source at a controlled acidic pH with pepsin from fish as the hydrolytic enzyme. The prior art shows that peptide composition contains a mixture of peptides which have aromatic acids in the N-terminal portion, wherein the aromatic acids are for example, phenylalanine and tyrosine produced by enzymatic hydrolysis of a protein source, for example, fish protein at pH of about 1.5 with pepsin having molecular weight of less than 10,000, for example 800 to 2,000 (See e.g. Figure 3, cols. 2-4 and claims 13-14 and 16).

With respect to independent claim 17, the claim is in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps. In re Brown, 173 USPQ (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). Thus, the prior art anticipates a process for making a product obtained through enzymatic hydrolysis of a protein source with pepsin enzyme derived from a fish protein, and as such, anticipates claims 17-20 as drafted.

5. Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita et al (Journal of Food Science, Vol. 41, No. 5, pp. 1029-1032, 1976).

The reference of Yamashita et al. discloses a bioactive composition produced by hydrolysis of a protein source at a controlled acidic pH with pepsin from fish as the hydrolytic enzyme. The prior art shows that peptide composition contains a mixture of peptides which have aromatic acids in the N-terminal portion, wherein the aromatic acids are for example,

phenylalanine and tyrosine produced by enzymatic hydrolysis of a protein source, for example, fish protein at pH of about 1.5 with pepsin having molecular weight of less than 10,000, for example lower molecular weight of 500 (See e.g. the entire document and especially pages 1029 and 1032).

With respect to independent claim 17, the claim is in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps. In re Brown, 173 USPQ (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). Thus, the prior art anticipates a process for making a product obtained through enzymatic hydrolysis of a protein source with pepsin enzyme derived from a fish protein, and as such, anticipates claims 17-20 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimaki et al. (U.S. Patent No. 4,016,147) or Yamashita et al (Journal of Food Science, Vol. 41, No. 5, pp. 1029-1032, 1976) taken with Gildberg et al. (Comp. Biochem. Physiol., Vol. 114B, No. 1, pp. 97-101, 1996).

The prior art of Fujimaki et al. or Yamashita et al. as discussed above under the rejection of 35 U.S.C. 102(b) each discloses a bioactive composition produced by hydrolysis of a protein source at a controlled acidic pH with pepsin from fish as the hydrolytic enzyme.

Fujimaki et al. or Yamashita et al. each differs from claims 17-21 in failing to teach the use of enzymatic hydrolysis of a fish protein source with pepsin enzyme derived from the stomach of Atlantic cod, however, Gildberg et al. teach the isolation of acid peptide fractions from a fish protein hydrolysate derived from the stomach of Atlantic cod (*Gadus morhua*) in which the isolated or separated acid peptide fractions were used *in vitro* stimulatory experiments with head kidney leukocytes from Atlantic salmon (*Salmo salar*). See e.g., abstract, material and methods and Figure 3. On page 98, the reference clearly discloses the process of treating a fish protein source with an acid such as HCl acid at pH 2-3, and for a time sufficient to effect bioactive peptide formation. On page 99, left column, last paragraph and on Table I, the reference shows that all the fractions contain peptides with high levels of acid amino acids and

aromatic amino acids such as tyrosine and phenylalanine. Thus, the reference teaches the use of the proteolytic enzyme derived from the stomach of Atlantic cod in the hydrolyzing of the fish protein at a controlled pH and a process for the production of bioactive peptide compositions having aromatic amino acids at the N-terminal position.

Thus, such features are known or suggested in the art, as seen in the secondary reference of Gildberg et al., and including such features into the methods of the primary references of Fujimaki et al. or Yamashita et al., which teach the use of such pepsin in the process of enzymatic hydrolysis of fish protein, so as to provide a product which is bioactive, would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

With respect to independent claim 17, the claim is in product-by-process format and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). Further, the prior art described the product as old, In re Best, 195 USPQ 430, 433 (CCPA 1977); (See MPEP 706.03 [e]). Hence, the burden of proving that the process limitation makes a different product is shifted to the Applicants, In re Fitzgerald, 205 USPQ 594.

In regard to the limitations recited in the claims such as the size of amino acid units; ranges of pHs, and molecular weights; it is conventional and within the ordinary skill of the art to which this invention pertains to select the appropriate amino acid units, ranges of pHs, and

molecular weights. Although, the prior art does not disclose the specific amino acid units, and the specific pH ranges and molecular weights for carrying enzyme hydrolysis as claimed. Nevertheless, the amino acid units and the ranges of pH and molecular weight disclosed by the prior art and claimed by Applicant overlap in scope, and as such, it is conventional and within the ordinary skill of the art to optimize or select the specific amino acid units, pHs, and molecular weights from ranges disclosed. See Ex parte Lee, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993); also, See MPEP 2131.03. Therefore, in view of the above, and in view of the combined teachings of the prior art; one of ordinary skill in the art would have been motivated at the time the invention was made to use the already known process for making a product obtained through enzymatic hydrolysis of a protein source such as fish with pepsin enzyme derived from the stomach of Atlantic cod and recover a peptide product which is bioactive, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDENCE

7. Claims 1-7-21 are rejected and claims 9 and 22-32 are withdrawn as non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
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Mohamed/AAM

June 24, 2002